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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,519	11/01/1999	SHIH CHUNG	AH0948Q	8808

7590 02/23/2004

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/431,519	CHUNG ET AL.	
	Examiner	Art Unit	
	Neil Levy	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 11/4/03

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The 112 rejection is maintained to the following extent. "derivatives" is open to wide interpretation (water, carbon dioxide are derivatives of estradiol) and thus is indefinite, Somatotrophin is presumably misspelled-otherwise, examiner is unfamiliar with this drug.

Applicant's arguments filed 11/28/03 have been fully considered but they are not persuasive. Applicants' argue for support for "derivatives"-but examiner finds no definition, only salts as the "such as" under the derivative language-water still holds, and the scope of claims over specification then would be at issue. As to the dual formulation-language now permits of separate formulations; as opposed to a single dosage form-either is seen as met by the current language.

Claims 1-5, 7-9, 13-15, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivy et al 4670949 in view of admission in the instant specification.

Ivy poses dual implant formulations, of anabolic agents, in controlled release and immediate release dosage forms. The general term Zearalin includes Zeranol (col.3, top col. 7 and claim 10).

Applicants arguments are in accord with "consisting essentially of " Somatatrophin and Zeranol. The rejection of record is thus maintained.

See example 1-an anabolic dual formulation composition, as of the instant invention (p.5, lines 6-90 comprising and immediate release first formulation consisting essentially of (example 1) somatotrophin (b GH) and (instant claim 8) RALGRO implanted sub Q Zeranol ((col.5) top) controlled release long acting anabolic agent (col.3, lines 47-51) with a controlled release agent, lactose, as identified in the instant specification as a RALGRO component. Table 5 shows ADG increased in treated versus control (O) animals. So the 2 dosage forms cooperate to effect stimulation.

The instant invention in general, is shown by Ivy, but the specific incorporation of claim 1 compounds is not. See above; Ivy uses zeranol, and somatotrophin, but instant claim 8 expands claim 1 to include somatotrophin, or derivatives of the listed anabolic agents. In this mode, Ivy provides the mix, at the ratios of instant claims 2-4 (col.4, lines 6-19) when zeranol is 200-600 and b GH @ 100.

Claims 1, 5, 7, 8, 9, 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'callaghan et al '86.

The rejection of record is maintained within the language of the invention as it is claimed, we find the O'callaghan implants, of the instant hormones, (claim 1) the same or different, in the separate formulations. We do not see how this is different from the claimed invention.

Sub Q cattle pellets, implantable, consisted of estrdiol and progesterone, estradiol, and trenbolone acetate, in 15 pellets (col.2, materials-p. 427). The formulations, although not labeled as immediate and controlled release, meet the claimed invention. The compounds, as used in all the devices as presented, are known

to immediately release the actives. The problem of concern is that of sustained release, effective lifespan varied from 90-120 days (p.427, 2nd ¶). Silastic was known to extend activity to 365 days, providing long acting, slow release, We would equate this effect with the instant term controlled release, and the instant controlled release agent, as silastic. In comparison, the instant term, "immediate" absent any identification of a specific time period associated with "immediate", is seen as anything less than the long acting, slow release-again both forms known by the artisan, to begin to release active immediately upon insertion in the body. Progesterone is also shown as a controlled – release agent (discussion, ¶ 2, p.429). Trenbolone acetate can readily be envisioned as the instant "immediate release" as it is in a carrier not of the estradiol controlled release silastic (p.428, ¶ 2, treatment (4) on p. 427). Although the instant claim is to a composition, in fact the disclosure is to multiple compositions, not part of the same composition, but are stated to be as a method, administered as an "implant" by simultaneous or successive administration. O'Callaghan so administers (4), p.427) an anabolic implant dual formulation composition as is the instant invention as claimed, when "composition" is not restricted to one unitary product; immediate release is not limited to only 1 formulation, or to any time frame. Immediate and controlled release are not exclusive terms. Controlled release does not exclude immediate release, and does not exclude slow or continued release. Dual refers to immediate and controlled functions, not to the number of formulations (the instant disclosure provides (example 2) multiple pellets. Cooperation was seen (p.428) when slow (controlled) release silicone estradiol implant was combined with Trenbolone acetate-increase in daily gain.

O'callaghan states that zeranol, in the compressed pellet (the O'callaghan controlled release form) was known to be implanted with Trenbolone acetate (the O'callaghan immediate release form), thus, instant claim 9 is met, as is 10 ((4) p.427).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'callaghan et al '86 in view of Nessel et al 3920806 stevens et al 5874098 and Dick et al GB 2167662.

This rejection is also maintained.

O'callaghan (above) provides the instant dual formulations, but does not describe the excipients, diluents, bulking agents etc., as they are implicitly present in the use of commercially avoidable and known implants of silastic, compressed pellets at p.427. Nessel shows one of these forms, stated to be a conventional lactose vehicle (col.2, lines 35-37) and shows that the lactose form provides over 2 times the release rate, even as early as 2 weeks (Table 1) over the polymer containing the instant derivative (claim 8) anabolic agent. Note, however, the Nessel polymers released 100% by 8 weeks; the problem O'callaghan attempts to solve, with extension to 52 weeks.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an implant for growth enhancement on cattle, to choose the combination of O'callaghan, as it provides in combination, enhanced effects over single formulations. The particular delivery forms are shown as art recognized, but in detail, were not described. Nessel shows, in the anabolic implant field lactose formulations are known, and known, and provide for immediate release, while polymer forms provide controlled release, the polymer prolonging release to 8 weeks only.

Stevens is cited to show implantation of multiple pellets (fig 1, 2) sub Q to cattle ear is well known, but it was also evident that the concept of an immediate release (quick release) and controlled, sustained release was (example) also known at the time of the instant invention. Stevens does show means of control of time of release (col.5, top and lines 43-56) by using additives, along with one or more pellets of one or more drugs, including growth hormone. These additives and excipients include lactose, ethylcellulose, binders, and coloring agents. Example 2 shows or compression pellet, of progesterone and estradiol as of O'callaghan. The fast release in this case was not an anabolic agent, however examples show controlled release to be attained by increasing the ratio and amount of active to that of Kamei (formula III and IV, or by using different actives (formula I and II).

Thus, were one to wish to have a biodegradable, implant of the O'callaghan type, it would have been obvious and within the purview of one in the implantation arts to utilize the Stevens ingredients, adjusting the pellets in terms of ratios of quick to controlled release, when the same active is desired, or to choose an immediately releasable compound, such as of Stevens or Trenbolone acetate of O'callaghan, with a controlled release formulation, such as the estradiol/progesterone examples, in order to achieve enhanced results as shown attainable by Callaghan, without the need at the time of Callaghan, of retained implant at slaughter (p.429, discussion). The ratio of polymer to active is shown as 8% (formula I , II , IV of Steven). Immediate to controlled release pellets are disclosed as 1 to 8 (col.5, lines 37-40). Thus, attainment of the benefits of a biodegradable polymer, as opposed to silastic, would be obvious for

one in the art to choose in order to reduce inflammation as shown associated with the silastics, utilize the required amount of initial or immediate release anabolic agent, such as Trenbolone acetate of O'callaghan, or b GH and otherwise optimize selection of anabolic agent compound and amount in order to provide less objectionable pressure of hormone at slaughter, in accord with public desire of for meat free additive, especially hormone.

Dick et al shows the residue problem was known (p.1, lines 17-31) and that prolonged delivery was not. Anabolic agents are of instant-zeranol, trestosterone, estradiol (p.1 lines 59-65) with one, or more than one agent effective, with ratios of 1:10 best.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's arguments filed 11/28/03 have been fully considered but they are not persuasive. Applicants arguments were considered, and addressed above, for continued rejections. We concur, with the consisting essentially argument for immediate release as having nothing to impede release, so the references showing polymer or encapsulates are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday through Friday from 7a.m to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/tgd

February 18, 2004

NEIL S. LEVY
PRIMARY EXAMINER